JUL 2 1 2004

8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Barry Wyshogrod Regulatory Engineer Philips Medical Systems Cardiac and Monitoring Systems 3000 Minuteman Road Andover, MA 01810	Tel: (978) 659-7383 Fax: (978) 685-5624 Email: barry.wyshogrod@philips.com
This summary was prepared on June 25, 2004.	

2. The name of this device is the Philips M3290A IntelliVue Information Center Software Release F.0 and M4840A Philips Telemetry System II with M4841A patient device. Classification names are as follows:

Classification	ProCode	Description
870.1025, II	74 DSI	Arrhythmia Detector and Alarm
870.1025, II	74 MHX	Physiological Monitor, Patient Monitor (with arrhythmia detection or alarms)
870.1025, II	74 MLD	Monitor, ST Alarm
870.1130, II	74 DXN	System, Measurement, Blood-Pressure, Non-Invasive
870.2300, II	74 MSX	System, Network and Communication, Physiological Monitors
870.2700, II	74 DQA	Oximeter
870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical
870.2910, II	74 DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency

3. The new device is substantially equivalent to the previously cleared M3290A IntelliVue Information Center Software and M4840A Philips Telemetry System II, cleared under K040357.

4. The modification is a change that adds support for an additional ECG chest lead (vector), adds NBP limit alarms, and adds support for additional network functionality.

5. The new device has the same Indications for Use as the legally marketed predicate devices:

   M3290A: For central monitoring of multiple adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

   M4840A: For ambulatory and bedside monitoring of ECG and SpO_2 parameters of adult and pediatric patients in healthcare facilities.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities have successfully established the performance, functionality, and reliability characteristics of the new devices with respect to the predicates. Testing involved system level tests, integration tests, environmental tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results successfully demonstrate that patient monitoring system functionality meets all reliability requirements and performance claims and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2004

Phillips Medical Systems
c/o Mr. Barry Wyshogrod
Regulatory Engineer
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810

Re: K041741
Trade Name: M3290A Intellivue Information Center Software Release F.0 and M4840A Phillips Telemetry System II including M4841A Patient Device
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II (two)
Product Code: MHX
Dated: July 8, 2004
Received: July 9, 2004

Dear. Mr. Wyshogrod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: M3290A IntelliVue Information Center Software Release F.0 and M4840A Philips Telemetry System II including M4841A patient device.

Indications For Use:

M3290A: For central monitoring of multiple adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

M4840A: For ambulatory and bedside monitoring of ECG and SpO_2 parameters of adult and pediatric patients in healthcare facilities to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

Neil R P Ogden

(Division Sign-Off)
Division of Cardiovascular Devices

for bjz

510(k) Number K041741

Prescription Use **Yes** AND/OR Over-The-Counter Use **No**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)